

**MOTRIN- ibuprofen 800mg tablet**  
**Advanced Rx Pharmacy of Tennessee, LLC**

-----  
**Ibuprofen 800mg tablets #120**

**Medication Guide Section**

**MEDICATION GUIDE FOR NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)**

What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

NSAIDs can cause serious side effects, including:

Increased risk of a heart attack or stroke that can lead to death. This risk may happen early in treatment and may increase:

with increasing doses of NSAIDs  
with longer use of NSAIDs

Do not take NSAIDs right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

Avoid taking NSAIDs after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:

anytime during use  
without warning symptoms  
that may cause death

The risk of getting an ulcer or bleeding increases with:

past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs  
taking medicines called “corticosteroids”, “anticoagulants”, “SSRIs”, or “SNRIs”  
increasing doses of NSAIDs  
longer use of NSAIDs  
smoking  
drinking alcohol  
older age  
poor health  
advanced liver disease  
bleeding problems

NSAIDs should only be used:

exactly as prescribed  
at the lowest dose possible for your treatment  
for the shortest time needed

What are NSAIDs?

NSAIDs are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as different types of arthritis, menstrual cramps, and other types of short-term pain.

Who should not take NSAIDs?

Do not take NSAIDs:

if you have had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAIDs.

right before or after heart bypass surgery.

Before taking NSAIDs, tell your healthcare provider about all of your medical conditions, including if you:

have liver or kidney problems

have high blood pressure

have asthma

are pregnant or plan to become pregnant. Talk to your healthcare provider if you are considering taking NSAIDs during pregnancy. You should not take NSAIDs after 29 weeks of pregnancy.

are breastfeeding or plan to breast feed.

Tell your healthcare provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins or herbal supplements. NSAIDs and some other medicines can interact with each other and cause serious side effects. Do not start taking any new medicine without talking to your healthcare provider first.

What are the possible side effects of NSAIDs?

NSAIDs can cause serious side effects, including:

See “What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?”

new or worse high blood pressure

heart failure

liver problems including liver failure

kidney problems including kidney failure

low red blood cells (anemia)

life-threatening skin reactions

life-threatening allergic reactions

Other side effects of NSAIDs include: stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting and dizziness.

Get emergency help right away if you get any of the following symptoms:

shortness of breath or trouble breathing

chest pain

weakness in one part or side of your body

slurred speech

swelling of the face or throat

Stop taking your NSAID and call your healthcare provider right away if you get any of the following symptoms:

nausea

more tired or weaker than usual

diarrhea  
itching  
your skin or eyes look yellow  
indigestion or stomach pain  
flu-like symptoms  
vomit blood  
there is blood in your bowel movement or it is black and sticky like tar  
unusual weight gain  
skin rash or blisters with fever  
swelling of the arms, legs, hands, and feet

If you take too much of your NSAID, call your healthcare provider or get medical help right away.

These are not all the possible side effects of NSAIDs. For more information, ask your healthcare provider or pharmacist about NSAIDs.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA1088.

#### Other information about NSAIDs

Aspirin is an NSAID but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.

Some NSAIDs are sold in lower doses without a prescription (over-the-counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

#### General information about the safe and effective use of NSAIDs

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NSAIDs for a condition for which it was not prescribed. Do not give NSAIDs to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information about NSAIDs, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about NSAIDs that is written for health professionals.

For more information, go to [www.amneal.com](http://www.amneal.com) or call 1-877-835-5472.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:

Amneal Pharmaceuticals Pvt. Ltd.

Oral Solid Dosage Unit

Ahmedabad 382213, INDIA

Distributed by:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

Rev. 06-2020-03

## Indications and Usage Section

### INDICATIONS AND USAGE

Carefully consider the potential benefits and risks of Ibuprofen Tablets and other treatment options before deciding to use Ibuprofen Tablets. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals [see WARNINGS].

Ibuprofen Tablets are indicated for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.

Ibuprofen Tablets are indicated for relief of mild to moderate pain.

Ibuprofen Tablets are also indicated for the treatment of primary dysmenorrhea.

Controlled clinical trials to establish the safety and effectiveness of Ibuprofen Tablets in children have not been conducted.

## Contraindications Section

### CONTRAINDICATIONS

Ibuprofen tablets are contraindicated in patients with known hypersensitivity to ibuprofen.

Ibuprofen tablets should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs.

Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients [see WARNINGS, ANAPHYLACTOID REACTIONS, and PRECAUTIONS, PREEXISTING ASTHMA].

In the setting of coronary artery bypass graft (CABG) surgery [see WARNINGS].

## Principal Display Panel

NDC 65162-**466**-03

# Ibuprofen Tablets, USP

**800 mg**

**PHARMACIST:**  
Dispense the Medication  
Guide provided separately  
to each patient.

**Rx only**  
**30 Tablets**



Each film-coated tablet contains:  
Ibuprofen, USP .....800 mg

**Usual Dosage:** See package insert for complete product information.

**Keep this and all drugs out of reach of children.**

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid excessive heat 40°C (104°F).

**Dispense** in a tight, light-resistant container as defined in the USP.

Mfg. Lic. No. G/25/2137

Manufactured by: **Amneal Pharmaceuticals Pvt. Ltd.**  
**Oral Solid Dosage Unit**  
Ahmedabad 382213, INDIA

Distributed by: **Amneal Pharmaceuticals LLC**  
Bridgewater, NJ 08807

Rev. 08-2017-02



65162 46603 4

Non-Varnish Area  
(For Lot And Exp. Date)  
(21 X 50.8 mm)

# MOTRIN

ibuprofen 800mg tablet

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:80425-0047(NDC:65162-466)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	800 mg

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	IP;466
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0047-5	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2009	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078558	11/23/2009	

**Labeler** - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

## Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0047)

Revised: 4/2021

Advanced Rx Pharmacy of Tennessee, LLC